

Dean L. Engelhardt et al.

Serial No. 07/960,071

Filed: October 13, 1993

Page 2 (Request for Reconsideration of Restriction Requirement  
and Election of Species Under 37 C.F.R. §1.143-September 13, 1993)

### **REMARKS**

Reconsideration of the restriction requirement and the election of species is respectfully requested.

Claims 204-237 are pending in the application. No claims have been amended, added or cancelled. Accordingly, claims 204-237 are presently under examination.

### **The Restriction Requirement Under 35 U.S.C. §121**

In the Office Action (pages 2 and 3), the Examiner required restriction to one of the following groups:

- I. Claims 204-208, 209-214, and 216-218, drawn to the nucleotide complex wherein Sig is selected from polysaccharides, classified in Class 536, subclass 55.1;
- II. Claims 204-208 and 219-220, drawn to the nucleotide complex wherein Sig comprises a radioactive isotope, classified in Class 536, subclass 40;
- III. Claims 204-208 and 221-222, drawn to the nucleotide complex wherein Sig comprises an enzyme, classified in Class 424, subclass 94.3;
- IV. Claims 204-208 and 223-224, drawn to the nucleotide complex wherein Sig comprises a fluorescent component, classified in Class 536, subclass 40;
- V. Claims 204-208 and 225-227, drawn to the nucleotide complex wherein Sig comprises a magnetic component, classified in Class 536, subclass 113;
- VI. Claims 204-208 and 228, drawn to the nucleotide complex wherein Sig includes a hapten component capable of complexing with an antibody, classified in Class 530, subclass 387;

VII Claims 204-208 and 229, drawn to the nucleotide complex wherein Sig includes a catalytic metal-containing component, classified in Class 536, subclass 121; and

VIII Claims 204-208 and 230-234, drawn to the nucleotide complex wherein Sig includes a polypeptide, classified in Class 530, subclass 350.

Applicants hereby elect, with traverse, Group III, claims 204-208 and 221-222, drawn to a nucleotide complex wherein Sig comprises an enzyme. Applicants respectfully request that the restriction requirement under 35 U.S.C. §121 be reconsidered and withdrawn in view of the remarks set forth below.

Applicants respectfully submit that the claims represented by all of Groups I-VIII, as set forth hereinabove, form a single general inventive concept which should properly be examined in the same application. Applicants contend that a diligent search of the art of any one of these groups, as classified by the Examiner, would necessitate a review of the art - at least in part - for the other corresponding groups. In fact, Groups I, II, IV and V, as classified by the Examiner, involve identical classes. Furthermore, Groups VI and VIII likewise involve identical classes.

Under MPEP §803, two criteria are necessary in order for a restriction requirement between patentably distinct inventions to be proper:

(1) The inventions must be independent or distinct as claimed;

and

(2) there must be a **serious burden** on the Examiner if restriction is not required.

It is respectfully submitted that a search of the prior art to include any of the non-elected nucleotides covered by Groups I-II, IV-VIII with the elected nucleotide of Group III, would not place a serious burden on the Patent Office or the Examiner in light of the search that will already be required for the provisionally elected claims 204-208 and 221-222. All of claims 204-237 ultimately recite the sugar moiety labeled nucleotide of claim 204, the only independent claim in this application. To require restriction in this instance, will - in effect - hamper the current prosecution because it draws attention away from the single general

Enz-5 (D5)(C)

inventive concept unifying all the pending claims, namely, a sugar moiety labeled nucleotide.

Furthermore, even assuming for the sake of argument, that the subject matter of claims defined by Groups I-II and IV-VIII, would entail, for example, a separate classification or status in the art from the subject matter of provisionally elected claims of Group III and claims 204-208 and 221-222, Applicants are firmly of the opinion that such a search, diligently would inevitably overlap with the subject matter covered by Group III. Because the Examiner is expected to carry out a diligent search of the prior art, Applicants submit that no serious burden would be imposed in terms of the search effort if he properly includes the subject matter of Groups I-II and IV-VIII together with the subject matter of Group III - because all eight groups define subject matter pertaining to the instant sugar moiety labeled nucleotide.

It is submitted, moreover, the instant restriction requirement will only serve to duplicate the search efforts of the Patent Office and other examiners in future filings necessitated by the requirement, in the event it is maintained. The instant Assignee will also be burdened unfairly by the additional cost for such future filings, the subject matter of all of which should be properly examined in the instant application.

Applicants sincerely believe that if the Examiner carefully considers the foregoing arguments, he too, will reasonably conclude that no burden in terms of search efforts will be placed upon the Patent Office or himself, if the claims of Groups I and IV-VIII are examined in this application, together with the claims of Group III. Applicants earnestly urge, therefore, that the Examiner withdraw the restriction requirement on the basis of the foregoing remarks.

Before passing on the restriction requirement, Applicants would like to bring to the Examiner's attention the issuance on August 31, 1993 of U.S. Patent No. 5,241,060 which is entitled "Base Moiety-Labeled Detectable Nucleotide." The instant application is related to the application underlying the aforementioned '060 patent by virtue of both being divisional applications in a family of applications, all of which derive their effective filing date from U.S. Application Serial No. 06/391,440, filed on June 23, 1982. A copy of U.S. Patent No. 5,241,060 is attached hereto as Exhibit A.

Dean L. Engelhardt et al.

Serial No. 07/960,071

Filed: October 13, 1993

Page 5 (Request for Reconsideration of Restriction Requirement  
and Election of Species Under 37 C.F.R. §1.143-September 13, 1993)

Applicants would like to point out that the issued claims contain dependent claims 13 and 31 which are directed to a nucleotide (in the case of claim 13) and a composition (in the case of 31) in which Sig (or a detectable moiety) is selected from the group consisting of biotin, iminobiotin, an electron dense component, a magnetic component, an enzyme, a hormone component, a radioactive component, a metal-containing component, a fluorescent component, a chemiluminescent component, an antigen, a hapten and an antibody component. Many of the Markush members recited in the dependent claims - a radioactive component, an enzyme, a fluorescent component, a magnetic component, a hapten and a metal-containing component - are now the subject of the instant restriction requirement (Groups II, III, IV, V, VI and VII). Furthermore, dependent claim 5 in U.S. Patent No. 5,241,060, is directed to "the nucleotide of claim 1 wherein Sig is selected from the group consisting of mono-, oligo- and polysaccharides," which Markush members are also cited in the instant restriction requirement (Group I). Finally, claims 26-30 in U.S. Patent No. 5,241,060 contain recitations of a polypeptide, such as represented by Group VIII in the instant restriction requirement.

#### **The Election of Species Requirement Under 35 U.S.C. §121**

In the Office Action (page 3), the Examiner stated that "[t]his application contains claims directed to the following patentably distinct species of the claimed invention: biotin or iminobiotin, an electron dense component, a magnetic component, an enzyme, a hormone component, a radioactive component, a metal-containing component, a fluorescent component, an antigen or a hapten and an antibody." The Examiner further stated that "Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 215 and claims 235-237 are generic.

Applicants hereby elect, with traverse, the species wherein Sig or the detectable moiety comprises an enzyme. Applicants respectfully request that the election requirement be reconsidered and withdrawn in view of the following remarks.

Applicants' undersigned attorney has reviewed the pending claims, and it appears that the elected species, a nucleotide or oligo- or

**Enz-5 (D5)(C)**

Dean L. Engelhardt et al.

Serial No. 07/960,071

Filed: October 13, 1993

Page 6 (Request for Reconsideration of Restriction Requirement  
and Election of Species Under 37 C.F.R. §1.143-September 13, 1993)

poly(nucleotide) comprising Sig or a detectable moiety that comprises an enzyme, is consonant with the elected claims of Group III, as set forth above, and as such, claims 204-208 and 221-222 are readable thereon. Thus, the Examiner's determination that claim 215 and claims 235-237 are generic, is a correct determination in light of the species elected by the Applicants.

Applicants note that the instant invention is directed to a nucleotide and an oligo- or polynucleotide (deoxy or ribo) in which Sig or a detectable moiety is attached to the sugar moiety of the nucleotide or of at least one nucleotide contained in the oligo- or polynucleotide. It is submitted that the claimed compositions are novel, useful and unobvious. It is respectfully submitted that the species of Sig or detectable moiety, which are disclosed and claimed in the instant application, form a single general inventive concept, when read in context with all of the pending claims and the instant disclosure. Moreover, the species of Sig or detectable moiety represent a reasonable number of species for the members of the group having characteristics in common, such that the generic subject matter for these members - and not single individual species - should properly be examined in the same application. In addition, Applicants contend that if the species recited in the generic claims, 215 and 235-237, are allowed, then the other species will also be found allowable as part of the generic claim. Applicants further contend that they are entitled to claim their invention as broadly as the prior art permits, commensurate with the disclosure requirements of 35 U.S.C. §112. Under such a well-established legal principle, Applicants are entitled to claim and to pursue the full breadth of their generically disclosed invention in the same application. Applicants request, therefore, that the Examiner reconsider and withdraw the species election, and examine the instant claims as originally filed.

#### **Submission of Information Disclosure Statement**

In order to comply with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their undersigned attorney, are preparing to file, as soon as possible, an Information Disclosure Statement under 37 C.F.R. §1.99. Such a statement will be filed as soon as one or two additional documents are received by the undersigned from a patent service.

Dean L. Engelhardt et al.

Serial No. 07/960,071

Filed: October 13, 1993

Page 7 (Request for Reconsideration of Restriction Requirement  
and Election of Species Under 37 C.F.R. §1.143-September 13, 1993)

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of both the restriction requirement and the election of species. Full examination of claims 204-237 on the merits is believed to be in order.

In order to expedite review by the Examiner, Applicants' attorney is filing this response, including the extension request, with The Patent and Trademark Office by Express Mail.

\* \* \* \* \*

Dean L. Engelhardt et al.  
Serial No. 07/960,071  
Filed: October 13, 1992  
Page 8 (Request for Reconsideration of Restriction Requirement  
and Election of Species Under 37 C.F.R. §1.143-September 13, 1993)

### **SUMMARY AND CONCLUSION**

Claims 204-237 are presented for further prosecution, the restriction requirement notwithstanding. No claims have been amended, added or cancelled by this Response.

This Response is accompanied by and includes a Request For a Three-Month Extension of Time. The Patent and Trademark Office is hereby authorized to charge Deposit Account No. 05-1135 for the requisite fee of \$840.00 for a large entity, as set forth in 37 C.F.R. §1.17(c). The Patent and Trademark Office is further authorized to charge Deposit Account 05-1135 for any other fees in connection with this Response and to credit any overpayment therein.

In view of the above discussion of the issues, Applicants respectfully submit that substantive examination of all the instant claims, 204-237, is in order. The Examiner is respectfully requested to telephone the undersigned attorney at (212) 856-0876 to discuss the subject application.

Respectfully submitted,



Ronald C. Fedus  
Registration No. 32,567  
Attorney for Applicants

ENZO THERAPEUTICS, INC.  
c/o Enzo Biochem, Inc.  
575 Fifth Avenue (18th Floor)  
New York, New York 10017  
(212) 856-0876